III. Remarks

A. Status of the Application

Claims 1-19 and 26-34 were previously pending. No claims have been added or canceled. Reconsideration of presently pending claims 1-19 and 26-34 is respectfully requested in light of the above amendments and the following remarks.

B. Double Patenting Rejections

Claims 1-19 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 101-103, 106-110, 112-113 of copending U.S. Patent Application Ser. No. 09/924,298. Applicants again acknowledge this provisional rejection and will address any double patenting issues if and when a double patenting problem comes to fruition.

C. §103 Rejections

1. The Pope and Larsen Patents

Claims 1-7, 10-19, 26-29, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,290,726 to Pope et al. ("the Pope patent") in view of U.S. Patent No. 5,782,832 to Larsen et al. ("the Larsen patent"). Applicants traverse this rejection for at least the following reasons.

The PTO provides in MPEP §2131 that:

> "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness."

The Examiner clearly cannot, using the Pope and Larsen patents, establish a prima facie case of obviousness with respect to these claims for at least the following reasons.

35 U.S.C. §103(a) provides, in part, that:

> "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that

> the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . ." (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

Independent claim 1 recites "a first component having an articular surface for articulated movement with the shell, the first component formed from a wear resistant first material, and a second component formed from a resilient second material, wherein the body member is adapted to articulate with respect to the shell such that one or more surfaces of the shell come into contact with the articular surface of the first component during articulation." The Final Office Action asserts that the Pope patent at Col. 11, ll. 13-63 "discloses that the substrate could be a super-hard material, a corrosion-resistant metal, ceramic or polymer material." Page 7 (emphasis original). However, this is clearly not the case. The portion of the Pope patent cited by the Final Office Action recites,

> [t]he cup 205, however, is depicted as an appropriate counter bearing material **without a diamond table**. The material for **the cup 205** could be any of those mentioned above as **appropriate counter bearing material, a superhard material, a corrosion-resistant metal, ceramic or a polymer material.**

Pope, col. 11, ll. 57-62. (emphasis added).

That is, the appropriate counter bearing materials (superhard material, corrosion-resistant metal, ceramic, and polymer materials) are not a substrate for the diamond particulate as suggested by the Final Office Action. Instead, the entire cup 205 is formed of the counter bearing material. The counter bearing material of the cup 205 bears against the diamond particulate of the femoral head 202. The counter bearing material of the cup 205 is not a substrate for forming the diamond particulate. In that regard, as explicitly stated in the excerpt above, the cup 205 does not include the diamond particulate or diamond table. Accordingly, the Pope patent clearly does not disclose that the substrate for the diamond particulate could be a polymer material.

Rather, as noted previously, the Pope patent describes in great detail the specific materials that may be utilized as substrates in forming the polycrystalline diamond compact articulation

surfaces. The Pope patent notes that finding materials suitable for use as a substrate for the polycrystalline diamond component surfaces disclosed is "a formidable task" and becomes "even more difficult" once biocompatibility constraints are taken into account. Col. 34, ll 1-21. The Pope patent identifies a number of metals as being suitable substrates. However, none of the metals described as being suitable substrates appear to be resilient materials as required by claim 1. For example, the Pope patent states:

> "The substrate 410 may be a suitable pure metal or alloy, or a cemented carbide containing a suitable metal or alloy as a cementing agent such as cobalt-cemented tungsten carbide. Preferably the substrate will be a metal with high tensile strength." Col. 22, Lines 53-57
>
> "The unique material properties of diamond and its relative differences in modulus and CTE compared to most potential substrate materials diamond make selection of an appropriate polycrystalline diamond substrate a formidable task. When the additional constraints of biocompatibility is placed on the substrate, the choice is even more difficult. Most biocompatible metals are not compatible with the material properties of synthetic diamond." Col. 34, Lines 2-9
>
> "In order to manufacture any polycrystalline diamond component, an appropriate substrate should be selected. For the manufacture of a polycrystalline diamond component to be used in a prosthetic joint, the inventors prefer use of the substrates listed in the table below.

TABLE 2

SOME SUBSTRATES FOR BIOMEDICAL APPLICATIONS

SUBSTRATE	ALLOY NAME	REMARKS
Titanium	Ti6/4 (TiAlVa) ASTM F-1313 (TiNbZr) ASTM F-620 ASTM F-1580 TiMbHf Nitinol (TiNi + other)	A thin tantalum barrier is preferably placed on the titanium substrate before loading diamond feedstock. Approved biocompatible material.
Cobalt chrome	ASTM F-799	Contains cobalt, chromium and molybdenum. Wrought product. Approved biocompatible material.
Cobalt chrome	ASTM F-90	Contains cobalt, chromium, tungsten and nickel. Approved biocompatible material.
Cobalt chrome	ASTM F-75	Contains cobalt, chromium and molybdenum. Cast product. Approved biocompatible material.
Cobalt chrome	ASTM F-562	Contains cobalt, chromium, molybdenum and nickel. Approved biocompatible material.
Cobalt chrome	ASTM F-563	Contains cobalt, chromium, molybdenum, tungsten, iron and nickel. Approved biocompatible material.
Tantalum	ASTM F-560 (unalloyed)	Approved biocompatible refractory metal.
Platinum	various	
Niobium	ASTM F-67 (unalloyed)	Approved biocompatible refractory metal.
Maganese	Various	May include Cr, Ni, Mg, molybdenum.
Cobalt cemented tungsten carbide	WC	Not approved in the U.S. for prosthetic applications at the time of writing.
Cobalt chrome cemented tungsten carbide	CoCr cemented WC	CoCr is an approved biocompatible material.
Cobalt chrome cemented chronte carbide	CoCr cemented CrC	CoCr is an approved biocompatible material.
Cobalt chrome cemented silicon carbide	CoCr cemented SiC	CoCr is an approved biocompatible material.
Fused silicon carbide	SiC	
Cobalt chrome molybdenum	CoCrMo	A thin tungsten or tungsten/cobalt layer is placed on the substrate before loading diamond feedstock.
Stainless steel	Various	Approved biocompatible material.

Cols. 35-36, Lines 1-50.

Accordingly, one skilled in the art would not modify the device of Pope to include the resilient layer 506 of the Larsen patent "formed of a resilient material such as synthetic rubber or other elastomeric material" because such materials are not indicated as being suitable substrates for the polycrystalline diamond compact surfaces of the Pope devices. Attempting to use such a resilient material as the substrate would likely destroy the intended function of the devices of the Pope patent—providing polycrystalline diamond compact articulation surfaces. Since this modification of the Pope patent would destroy the purpose or function of the invention disclosed, there is no reason for one of ordinary skill in the art to make the claimed modification.

Therefore, for at least these reasons a prima facie case of obviousness has not been established with respect to independent claim 1. Claims 3-17 depend from and further limit

claim 1. Thus, Applicants respectfully request that the §103 rejection of claims 1 and 3-17 over the Pope and Larsen patents be withdrawn.

Similarly, independent claim 2 recites in part, "a first component having an articular surface for articulated movement with the shell, the first component formed from a wear resistant first material, and a second component formed from a resilient second material, wherein the second component is disposed between the first component and a third component also formed from the first material, the third component having an articular surface for articulated movement with the shell." As shown above, modifying the Pope patent in light of the Larsen patent, as suggested by the Office Action, would destroy the purpose or intended function of the invention disclosed. Accordingly, there is no reason for one of ordinary skill in the art to make the claimed modification. Further, with respect to claim 2 the resilient component is positioned between the first and second components having articulating surfaces. In contrast, the resilient layer 506 is positioned between support members 502, 504 that are fixed or fused to the vertebrae and do not articulate. No reason has been established for utilizing the resilient layer 506 with articulating components as required by claim 2. Therefore, for at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 2. Claims 18 and 19 depend from and further limit claim 2. Thus, Applicants respectfully request that the §103 rejection of claims 2, 18, and 19 over the Pope and Larsen patents be withdrawn.

With respect to independent claim 26, the Pope patent at least fails to teach, "a first portion configured to articulate with a first surface of the shell structure, the first portion formed from a first wear-resistant material; a second portion configured to articulate with a second surface of the shell structure, the second portion formed from a second wear-resistant material; and a third portion positioned at least partially between the first and second portions to avoid contact with the shell structure, the third portion formed from a resilient material." As shown above with respect to independent claims 1 and 2, modifying the Pope patent as suggested by the Office Action would destroy one of the intended functions of the Pope patent—providing polycrystalline diamond compact articulation surfaces. Therefore, for at least the same reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 26.

Claims 27-29, 32, and 33 depend from and further limit claim 26. Thus, Applicants respectfully request that the §103 rejection of claims 26-29, 32, and 33 over the Pope and Larsen patents be withdrawn.

2. The Pope, Larsen, and Buttner-Janz Patents

Claims 30 and 31 stand rejected under 35 U.S.C. §103 as being unpatentable over the Pope patent in view of the Larsen patent in further view of U.S. Patent No. 5,401,269 to Buttner-Janz et al. ("the Buttner-Janz patent"). However, as shown above the Pope and Larsen patents are insufficient to establish a *prima facie* case of obviousness with respect to independent claim 26, from which claims 30 and 31 depend and further limit. The Buttner-Janz patent does not affect this deficiency. Thus, for at least the same reasons, a *prima facie* case of obviousness has not been established with respect to claims 30 and 31. Therefore, Applicants respectfully request that the §103 rejection of claims 30 and 31 over the Pope, Larsen, and Buttner-Janz patents be withdrawn.

3. The Pope, Larsen, and Suddaby Patents

Claim 34 stands rejected under 35 U.S.C. §103 as being unpatentable over the Pope patent in view of the Larsen patent in further view of U.S. Patent No. 6,395,034 to Suddaby ("the Suddaby patent"). Claim 34 recites "a first portion configured to articulate with the first half of the shell structure, the first portion formed from a first wear-resistant material and having at least one recess; a second portion configured to articulate with the second half of the shell structure, the second portion formed from the first wear-resistant material and having at least one projection adapted to slidably engage with the at least one recess of the first portion; and a third portion positioned at least partially between the first and second portions, the third portion formed from a resilient material." Again, one skilled in the art would not modify the device of Pope to include the resilient layer 506 of the Larsen patent "formed of a resilient material such as synthetic rubber or other elastomeric material" because such materials are not indicated as being suitable substrates for the polycrystalline diamond compact surfaces of the Pope patent. Attempting to use such resilient materials as the substrate would likely destroy one of the intended functions of the devices of the Pope patent—providing polycrystalline diamond

compact articulation surfaces. Thus, there is no reason for one of ordinary skill in the art to make the claimed modification. The Suddaby patent does not affect this deficiency. Accordingly, for at least these reasons a prima facie case of obviousness has not been established with respect to claim 34. Therefore, Applicants respectfully request that the §103 rejection of claim 34 over the Pope, Larsen, and Suddaby patents be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Final Office Action have been addressed, and that claims 1-19 and 26-34 are in condition for allowance. Thus, an indication of allowance of the claims is respectfully requested.

Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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